UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO CASES LISTED IN EXHIBIT A OF DEFENDANTS' MOTION**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **Joseph R. Goodwin** **UNITED STATES DISTRICT JUDGE**

DEFENDANTS JOHNSON & JOHNSON AND ETHICON, INC.'S REPLY IN SUPPORT OF MOTION TO EXCLUDE PEGGY PENCE, PH.D.

Plaintiffs' brief does not seriously refute the well-settled legal principles cited in Ethicon's brief as a basis to exclude Dr. Pence's testimony.[1] Ethicon files this reply to address two discreet issues: (1) Dr. Pence's failure to account for what physicians already know, and (2) Dr. Pence's reliance on GHTF Guidelines for her opinion that Ethicon should have warned of the frequency and severity of the risks.

ARGUMENT

A. Dr. Pence's testimony should be excluded because she failed to consider physicians' preexisting knowledge of the risks.

In Plaintiffs' response, they argue that "[t]here is nothing in any regulation, guidance, or industry standard that allows a device manufacturer to omit a warning or adverse event based on the fact that doctors may already know about the risk." [Doc. 2172, p. 6]. This is not true.

The FDA device regulations, quoted in the expert report of Mr. Timothy A. Ulatowski,

[1] Some of Plaintiffs' brief is nonresponsive to the arguments raised here. For instance, Plaintiffs claim that "Ethicon dickers only with Dr. Pence's characterization of the seven incidents detailed in her Report as being 'representative' of the rationale's [sic] applied by Ethicon in the other thirty-two instances." [Doc. 2172, p. 10]. This argument was not raised in Ethicon's motion in these cases. Plaintiffs appear to have copied this portion of their brief from their response brief in the *Lewis* case, where this argument was at issue. *See Lewis v. Ethicon*, No. 2:12-cv-04301, Doc. 166, p. 29 (S.D. W. Va. Dec. 27, 2013).

M.S., explicitly provide that information commonly known to the device's users need not be included in a device's labeling:

> (c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: ***Provided, however, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device***.

21 C.F.R. §801.109(c) (emphasis added), *quoted in, e.g.*, Ulatowski TVT-O Report, p. 28, Ex. A; *see also* J. Agar, *Labeling of Prescription Devices for the Food and Drug Administration and Product Liability: A Primer-Part I*, 45 Food Drug Cosm. L.J. 447, 455 (1990) ("the trier of fact will determine the reasonableness of the omission").

But irrespective of the regulations, Dr. Pence's opinions do not comport with the law to be applied by the jury in these cases. This issue is critical, because expert testimony which fails to rest on the proper legal standard is inadmissible. *See* Memorandum in Support of Defendant Johnson & Johnson and Ethicon Inc's Motion to Exclude Peggy Pence Ph.D. [Doc. 2078, pp. 6-7]. Plaintiffs cite nothing to rebut the authorities cited in Ethicon's brief on this point.

It is a well-settled common law principle that there is no duty to warn of risks already known by the foreseeable user of the product. *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j; *Brooks v. Medtronic, Inc*., 750 F.2d 1227, 1230 (4th Cir. 1984) (no duty to warn of characteristics "well known to the medical community"); *Brown v. Drake-Willock Int'l, Ltd*., 530 N.W. 2d 510 (Mich. App. 1995) (citing regulation and finding

that physicians are sophisticated users).[2]

This is an objective test which does not depend on the knowledge of the individual user. *See* 3A Am. Jur. 2d *Products Liability* § 1055 ("A supplier has no duty to warn of risks involved in a product's use that are commonly known to foreseeable users, even if some users are not aware of them"). Individual knowledge is a causation issue.

Dr. Pence has expressly admitted that she does not know what knowledge physicians had and, in her analysis of the warnings, she did not take that knowledge into account. Her testimony rests on the erroneous assumption that there is no such exception to the duty to warn. Simply put, her opinions do not "fit" the law of the case, and so they should be excluded in their entirety.

B. Dr. Pence's opinion that Ethicon had a duty to warn of the frequency and severity of risks is unreliable.

In support of their argument that Ethicon should have warned of the frequency or severity of the risks, Plaintiffs point to the GHTF document "Essential Principles of Safety and Performance of Medical Devices, November 2, 2012." However, this document is not on point.

Though it is true that this particular GHTF document defines "risk" as the "combination

[2] *See also, e.g.*, 2-12 Frumer and Friedman, PRODUCTS LIABILITY §12.07[1][a] (2016); N.J. Stat. Ann § 2A58C:4 (1987) ("[a]n adequate product warning or instruction is one that . . . communicates adequate information on the dangers and safe use of the product, . . . taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician"); Conn. Gen. Stat. § 52-572q (b)(2) (2008) (factor to be considered in determining whether warning required is "the ability of the product seller to anticipate that the expected product user would be aware of the product risk, and the nature of the potential harm"); Kan. Stat. Ann. § 60-3305 (2007) (no duty to warn about risks "which a reasonable user or consumer of the product, with the training, expertise, experience, education and any special knowledge the user or consumer did, should or was required to possess"); *Guevara v. Dorsey Labs.*, 845 F.2d 364, 367 (1st Cir. 1988) (summary judgment for defendant based on "the general level of knowledge existent in the target [medical] community"); *Huskey v. Ethicon, Inc.*, No. 2:12-CV-05201, 2015 WL 4944339, at *7 (S.D. W. Va. Aug. 19, 2015) ("The medical device manufacturer, however, need not warn about 'risks already known to the medical community'") (Illinois law) (citation omitted); *Carlin v. Superior Court*, 920 P.2d 1347, 1354 (Cal. 1996) ("a pharmaceutical manufacturer may not be required to provide warning of a risk known to the medical community"); *Zachary v. Dow Corning Corp.*, 884 F. Supp. 1061, 1065 (M.D. La.1995) ("the duty to warn in the learned intermediary context requires an adequate warning of inherent dangers not within the knowledge of or obvious to the average learned intermediary").

of the probability of occurrence of harm and the severity of that harm," the purpose of this document was not to provide guidance on device labeling. [Doc. 2172-3, p. 9]. Rather, that guidance document was intended to describe "fundamental design and manufacturing requirements." [Doc. 2172-3, p. 6]. As this Court has observed, the GHTF guidance that is actually applicable to labeling, the GHTF's Label and Instructions for Use for Medical Devices [Doc. 2075-9], contains no such requirement. *See Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, *26 (S.D. W. Va. Apr. 28, 2015). Dr. Pence's opinion is unreliable and should be excluded.

CONCLUSION

For these reasons, and those stated in Ethicon's motion and memorandum in support, Ethicon respectfully requests that Dr. Pence's testimony be excluded in its entirety.[3]

[3] Ethicon notes that in their response brief [Doc. 2172], Plaintiffs state that "Defendants have moved to exclude Dr. Pence's testimony in the entirety, but have also offered six specific areas of testimony which they request be excluded." [Doc. 2172, p. 5]. To clarify, the six sections of Defendants' brief address the six areas of Dr. Pence's opinions offered in her expert reports. *See* Doc. 2078, pp. 1-2 (explaining the six subjects of Dr. Pence's testimony and how they correspond to the sections of the memorandum). If the Court excludes each of these six areas of testimony, then Dr. Pence's testimony should be excluded in the entirety in all cases.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this day, I electronically filed this document with the Clerk of the Court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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